95th Congress
2d Session

COMMITTEE PRINT

COMMITTEE PRINT No. 95-74

H.R. 1963—THE SUBSTITUTE PRESCRIPTION DRUG ACT

REPORT

OF THE

SUBCOMMITTEE ON CONSUMER PROTECTION AND FINANCE

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

NINETY-FIFTH CONGRESS

SECOND SESSION

DECEMBER 1978

U.S. GOVERNMENT PRINTING OFFICE
37-246 WASHINGTON : 1978

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H.R. 1963—The Substitute Prescription Drug Act

The Subcommittee on Consumer Protection and Finance held 2 days of hearings on H.R. 1963, The Substitute Prescription Drug Act, during the 95th Congress. H.R. 1963 would allow, but not require, pharmacists to substitute a less expensive, equivalent drug product for one prescribed by trade name. (Such drug products, that is, those with different trade names that have the same therapeutic effect, are generally referred to as "generic" drugs).

The majority of the witnesses supported legislation to allow drug substitution, but stated that such legislation should be enacted on the State level and that Federal action should be deferred pending further experience with State laws.

The subcommittee did not markup H.R. 1963 during the 95th Congress. The subcommittee recommends that during the 96th Congress, the committee evaluate the progress of the States in enacting substitution laws. Should there be inadequate progress at the State level, the subcommittee should again consider the advisability of enacting substitution legislation at the Federal level. In addition to considering the number of States which have approved such legislation, careful attention should be given to the specific provisions of the State statutes, actual experience under State Law, and the success of Federal agency projects regarding the substitution of equivalent drug products for trade name drugs.

This report briefly summarizes the proposed Federal legislation and current State and Federal activity with respect to drug substitution. It identifies the principal issues which remain to be resolved in shaping Federal legislation.

SUMMARY AND STATUS OF H.R. 1963

The bill under consideration provided that a pharmacist may substitute an equivalent drug product for a drug product prescribed by trade name, unless either the prescribing physician or the patient prohibit substitution. If the pharmacist makes the substitution, the drug must be the lowest cost equivalent drug product in the inventory of the pharmacist. A prescription written by an established (or "generic") name rather than a trade name must be filled with the lowest cost drug product in the pharmacist's inventory. State laws which prohibit a pharmacist from substituting a therapeutically and chemically equivalent drug product in accordance with the provisions of the act would be preempted. Violation of the substitution provisions would be a violation of the Federal Trade Commission Act.[1]

The bill was referred to the Subcommittee on Consumer Protection and Finance at the beginning of the Congress and the subcommittee held hearings on June 22 and July 27, 1978. In December 1977 the bill

[1] Violations of the Federal Trade Commission Act (15 U.S.C. § 41 et seq.) subject a person to cease and desist orders with up to $10,000 in civil penalties for violation of the orders; to civil penalties for violation of FTC rules; to injunctions prohibiting violations of the act; and to a requirement to make such redress for injury as may be required by a court.

was also referred to the Subcommittee on Health and the Environment. The Health Subcommittee received testimony on the bill in conjunction with hearings held on the Drug Regulatory Reform Act during 1978.

STATE ACTIVITY

In the mid-1950's, most States passed laws to prohibit the filling of prescriptions with anything other than the prescribed trade name drug product. Such laws were enacted to combat counterfeiting. Drugs, with the same shape, color, and packaging were frequently substituted for and claimed to be the originals. However, the antisubstitution laws, coupled with the prescribing habits of practitioners, had the effect of assuring a market for widely promoted and accepted trade name drugs. Because the "established" (or "generic") name of a drug is often complicated and difficult to remember, prescribers frequently find it easier to learn and remember a single, shorter trade name. (For example, Librium is a trade name for chlordiazepoxide hydrochloride; Cortane for brompheniramine maleate; Bax for diphenhydramine hydrochloride; and Sumycin for tetracycline hydrochloride). Practitioners often prescribe by a trade name because it is the name by which they readily identify the drug.

In 1976 the Consumer Protection and Finance Subcommittee held hearings regarding a variety of drug pricing proposals, including proposals to allow substitution of generic drugs for prescribed trade name drugs. At that time, the subcommittee heard testimony that 21 States had taken action to repeal their antisubstitution laws or to enact legislation providing for substitution.

During the 1978 hearings, testimony was received that 40 States have adopted laws allowing substitution. This is an impressive trend of State activity and the subcommittee hopes that it will continue. Largely because of this strong movement among the States in enacting substitution legislation, the subcommittee deferred legislative action in the 95th Congress. The specifics of the statutes vary substantially from State to State, therefore, the wide range of experience under the State statutes will provide invaluable information for future study.

FEDERAL AGENCY ACTIVITY

The staff of the Federal Trade Commission (FTC) is conducting a 2-year investigation of issues related to drug substitution. A model State law is to be drafted based on the results of the study, and the Chairman of the Commission told the subcommittee that the agency will make the results of the study available to State legislatures which seek assistance in drafting or revising State laws. It is currently predicted that the study and model code will be available at the end of December 1978.

The Commissioner of the Food and Drug Administration (FDA) told the subcommittee that his agency is cooperating in the development of a model drug act. Further, the FDA is currently updating a list of therapeutically equivalent drugs. Such a list will be useful to those States which seek guidance in developing lists of drug products that can be safely substituted. The FDA Commissioner stated at the hearing that the project would be completed by the end of October 1978. Unfortunately, the Commissioner's estimated timetable was overly optimistic for on December 4, 1978, he stated:

I must report with regret that its completion will take several weeks longer than I originally estimated; we now expect it to be available for distribution in December 1978. The delay results from our effort to insure that the data are accurate and up to date.[2]

Because of the invaluable assistance which such a list will provide to the States, the subcommittee urges the FDA to complete the list as soon as possible.

CONCLUSIONS

As a general proposition, the substitution of equivalent drug products for drugs prescribed trade name is desirable. Substitution will save consumers money. However, the amount of these savings will depend upon the particular provisions of the legislation and the actual practice of physicians, pharmacists, and consumers.

The overall potential for cost savings depends upon two characteristics of the prescription drug market: (1) the proportion of prescribed brand name drugs for which lower priced generic or alternate brand name sources exist, that is, the proportion of "multiple-source" drugs, and (2) the actual price spreads between prescribed drug products and their available substitutes, both within and between competing pharmacies.

For the Nation as a whole, some 60 percent of the most frequently dispensed drugs are now available on a multisource basis.[3] Witnesses presenting studies of drug substitution in Michigan, Wisconsin, and Delaware indicated that approximately one-half of the prescriptions written in those States are for multiple-source drug entities. As to actual price spreads, studies in the files of the subcommittee document price differentials amounting to hundreds of percentage points between particular brand name drugs and their generic substitutes. Thus the potential savings are indisputably quite large.

The extent to which these potential savings will be realized in practice depends upon (1) provisions as to physicians' options to require that prescriptions be "dispensed as written," and the manner and degree in which these options are exercised, (2) requirements and pharmacists' practices regarding the maintaining of an inventory of low-cost substitutes, (3) provisions and options regarding the extent to which cost savings are actually passed on to consumers, and (4) the extent to which consumers exercise their options to have prescriptions dispensed as written, or choose substitutes (whether by preference or lack of information) which are not the lowest cost alternatives.

Thus far, under the various State laws permitting drug product selection, realized cost savings appear to have been substantial, but they have nowhere begun to approach the potential savings. Thus, while the Michigan experience has demonstrated that savings of about 20 percent are realized for all prescriptions for which substitution actually occurs, the rate of substitution has been limited during the first 2 years of the State's substitution law to some 1.5 percent of all prescriptions for multiple-source drug entities. Somewhat less definitive results from Delaware, however, indicate a substantially higher rate of substitution (23.9 percent of multiple-source prescriptions) and a

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[2] Letter from Donald Kennedy, Commissioner of Food and Drugs, Department of Health, Education and Welfare, December 4, 1978. (In response to letter from Bob Eckhardt, chairman of the Subcommittee on Consumer Protection and Finance, October 12, 1978).

[3] I.M.S. America, Ltd., National Prescription Audit. (1976) (The National Prescription Audit is conducted annually by IMS America, Ltd., of Amber, Pa.).

higher percentage of per dosage savings from substitution (44 percent on seven products where price differences were statistically significant). The lower rate of substitution in Michigan has likely been the result, in part, of a provision in the original law, subsequently changed, which was interpreted as requiring a specific request by the consumer before substitution could be carried out by the pharmacist.

Witnesses who appeared at the hearing were asked to address the issue of whether or not "generic" drugs could be safety substituted for drugs prescribed by trade name. Those who addressed the question generally agreed that such drugs can be substituted for trade name drugs—with the limitation that there is a population of drugs that present problems of bioequivalency[4] dna a population of drugs about which it is simply unknown whether or not there are bioequivalency problems. There was greater disagreement as to the proper manner in which to handle the small population of inequivalent drugs than there was with respect to the question of allowing substitution. For example, some witnesses proposed establishing a list of drugs which can be substituted for others ("positive formulary"), other witnesses suggested a list of drugs which cannot be substituted ("negative formulary"), and still others proposed reliance on the pharmacist's judgment as embodied in H.R. 1963.

In addition to the sponsor of H.R. 1963, the witnesses who testified in favor of substitution were the following:

The Chairman of the Federal Trade Commission, who recommended—

. . . the adoption of a "positive formulary," a list of generic drugs products that are safe, effective and therapeutically equivalent to the brand-name products * * * Such lists help the pharmacist, who is the most logical person to search out the lower cost substitutes, to choose safely. And through vigorous FDA enforcement of quality control, the pharmacist can be confident of the continuing reliability of these lists. Thus, we recommend that H.R. 1963 define a "substitute drug" as one which is deemed equivalent by the FDA formulary.

The Commissioner of the Food and Drug Administration, who specified that the agency can—

. . . evaluate therapeutic equivalence only among those multsource drugs that have passed through the most stringent and modern version of the drug approval process. Thus, only post-1962 drugs that are the subject of new drug applications (NDA's) and pre-1962 drugs that are the subject of NDA's or abbreviated new drug applications (ANDA) have been or will be included in formulary lists provided by FDA to assist the States.

When the FDA states that a list of drugs is considered therapeutically equivalent the agency means, in short—

. . . that whether a drug is or is not a brand-name product has no influence on the probability that it will be deficient in some quality measure.

The Dean of the University of Alabama School of Medicine, who presented the conclusions of the Drug Research Board of the National Academy of Sciences. Based on data examined by the Board, in 1974 the Board approved a resolution "endorsing substitution of an equivalent drug product by the pharmacist, if the prescribing physician has no objection." The Dean stated that as long as drugs fall within the specifications set forth by the FDA regarding therapeutic equivalency, he was satisfied with the drug's equivalency for "clinical purposes" absent contrary evidence.

[4] That is, the effectiveness level of a drug and the level at which it becomes toxic are so close that normal manufacturing tolerances may not be sufficient to avoid differences in bodily effect from batch to batch or manufacturer to manufacturer.

A physician from the Mid-Westside Neighborhood Health Services Program in New York City.

The legislative representative for the National Retired Teachers Association and the American Association of Retired Persons, which have actively sought substitution legislation throughout the States.

The Executive Director of the National Association of Pharmaceutical Manufacturers.

The Executive Director of the American Pharmaceutical Association.

Substitution was opposed by the Pharmaceutical Manufacturers Association. The association stated—

> . . . neither manufacturers nor the Food and Drug Administration can guarantee that prescription products with identical generic names will perform in the same manner * * * Consumers cannot be assured today that a substituted product will perform as well as the prescribed item. Despite advances in technology, the question of comparative drug product quality and performance still remains troublesome.

Any legislation which is enacted must be drafted to provide protection against substitution of those drug products which cannot be substituted for other drugs. Remaining to be resolved is how to assure that those drugs with bioequivalency problems are not interchanged, and the extent to which the FDA must monitor and assist in providing assurances of bioequivalency.

RECOMMENDATIONS FOR FURTHER INQUIRY

If State legislative efforts are inadequate, either measured in terms of the number of States taking legislative action or the practical effect of such laws in assuring consumer savings by facilitating substitution, then the data currently being developed should be further analyzed to shape Federal legislation. This analysis should include the results of the study by the Federal Trade Commission, the recommendations of the Food and Drug Administration, and the practical functioning of the State acts. It should address, at a minimum, the following questions:

1. Should substitution be required, or only voluntary?

2. Is language requiring that a certain amount of the savings be passed on to consumers desirable? What amount should be required to be passed on? How can such a requirement be enforced?

At the hearings a consensus began to emerge between witnesses and members of the subcommittee that a requirement for cost savings pass through is not necessary; rather, competitive forces should assure that consumers enjoy cost savings. Therefore, the subcommittee during the 96th Congress should examine the experience with State cost pass through requirements to learn whether or not the most recent experiences contradict that consensus.

3. How should prescribers be allowed to require that the trade name drug be dispensed? By a handwritten statement to "dispense as written?" By a checkoff on the prescription form?

4. Should legislation include a "positive formulary" (a list of drugs to be substituted), a "negative formulary" (a list of drugs that should not be substituted), or no list at all? What is the proper role and responsibility of the FDA in providing the public with proper assurances of bioequivalency in substituted drugs?